UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,936	09/22/2003	John Moberg	1001.1715101	1606

28075 7590 02/03/2009

CROMPTON, SEAGER & TUFTE, LLC
1221 NICOLLET AVENUE
SUITE 800
MINNEAPOLIS, MN 55403-2420

EXAMINER	
LALLI, MELISSA LYNN	

ART UNIT	PAPER NUMBER
3728	

MAIL DATE	DELIVERY MODE
02/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/667,936	MOBERG, JOHN	
	Examiner	Art Unit	
	MELISSA L. LALLI	3728	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7-13,19-21 and 24-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7-13,19-21 and 24-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Amendment submitted on October 29, 2008 has been acknowledged. Canceled claims 14-18 are entered. Therefore, claims 1-4, 7-13, 19-21, and 24-26 are pending.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

3. Claims 1, 7-13, and 26 are finally rejected under 35 U.S.C. 102(b) as being anticipated by Roll.

Regarding claim 1, Roll discloses an elongate medical device (fig. 2) suitable for packaging in a tubular member (106) having a lumen defined by an inner surface, the elongate medical device comprising: an elongate shaft (113), a hub assembly (104) connected to the elongate shaft and including a portion manufactured from a first material; and an interference fit member (105) including a second material (abstract, line 19) and disposed about a portion of the hub assembly and configured to form an interference fit with the inner surface of the tubular member when the elongate shaft and the interference fit member (IFM) are disposed within the lumen of the tubular member (fig. 3).

Regarding claims 7-13, Roll discloses the second material (rubber) being more compressible than and readily deformable compared to the first material (fig. 2). Rubber is an elastomeric material and the IFM is disclosed as being an O-ring (col. 3, lines 6-10). Silicone is a form of rubber. The O-ring can be considered a bead adhered to the first material or an elongated elastomeric sleeve.

Regarding claim 26, Roll discloses an elongate medical device packaging assembly (fig. 2) comprising: a tubular member (106) having a lumen defined by an inner surface, an elongate shaft (113) with a proximal portion, a hub assembly (104) connected to the proximal portion of the elongate shaft and including a portion manufactured from a first material; and an IFM (105) including a second material (abstract, line 19) and disposed about a portion of the hub assembly and configured to form an interference fit with the inner surface of the tubular member when the elongate shaft and the IFM are disposed within the lumen of the tubular member (fig. 2).

Claim Rejections - 35 USC § 103

4. Claims 1-4, 7-11, 13, 19-21, and 24-26 are finally rejected under 35 U.S.C. 103(a) as being unpatentable over McGlinch et al. (McGlinch) in view of Gadberry et al. (Gadberry).

Regarding claim 1, McGlinch discloses an elongate medical device (20) suitable for packaging in a tubular member (10) having a lumen (14) defined by an inner surface, the elongate medical device comprising: an elongate shaft (22), a hub assembly (30) connected to the elongate shaft and including a portion manufactured from a first material (col. 3, lines 13-18); and an IFM (40) disposed about a portion of the hub assembly and configured to form an interference fit with the inner surface of the tubular member when the elongate shaft and the IFM are disposed within the lumen of the tubular member (fig. 1). McGlinch does not disclose the IFM including a second material; however, Gadberry discloses a similar elongate medical device (12) suitable for packaging in a tubular member (23) with an IFM (65) including a second material

(figs. 3 and 6, the IFM is readily deformable compared to the tubular member). It would have been obvious to one having ordinary skill in the art at the time of the invention to have substituted the IFM (65) including a second material of Gadberry for the IFM (40) of McGlinch in order to create an air tight seal when enclosing the elongate medical device as taught by Gadberry (col. 5, lines 33-36).

Regarding claim 2, McGlinch discloses the hub assembly (30) having a distal portion including a segment with a generally circular cross section including a first material (fig. 1). Gadberry discloses the IFM (65) being disposed about a channel (64) extending circumferentially around the tubular member (23). It would have been obvious to one having ordinary skill in the art at the time of the invention to have incorporated the channel (64) of Gadberry on the circular segment of the distal portion of the hub assembly (30) of McGlinch in order to facilitate removal of the elongate medical device from the tubular member while creating the appropriate amount of friction to keep the seal air tight when the elongate medical device is enclosed as taught by Gadberry.

Regarding claim 19, McGlinch discloses an elongate medical device (20) suitable for packaging in a tubular member (10) having a lumen (14) defined by an inner surface, the elongate medical device comprising: an elongate shaft (22) having a proximal portion, a hub assembly (30) connected to the proximal portion of the elongate shaft and including a portion manufactured from a first material (col. 3, lines 13-18); and a circumferential IFM (40) configured to form an interference fit with the inner surface of the tubular member when the elongate shaft and the IFM are disposed within the lumen

of the tubular member (fig. 1). McGlinch does not disclose the hub assembly including a circumferential channel and the IFM being disposed about a portion of the circumferential channel and comprising an elastomeric material; however, Gadberry discloses a similar elongate medical device (12) suitable for packaging in a tubular member (23) with a circumferential IFM (65) disposed about a circumferential channel (64) and comprising an elastomeric material (figs. 3 and 6, the IFM is readily deformable compared to the tubular member). It would have been obvious to one having ordinary skill in the art at the time of the invention to have substituted the circumferential channel (64) and elastomeric IFM (65) arrangement of Gadberry for the IFM (40) on the hub assembly (30) of McGlinch in order to facilitate removal of the elongate medical device from the tubular member while creating the appropriate amount of friction to keep the seal air tight when the elongate medical device is enclosed as taught by Gadberry.

Regarding claims 3, 4, 20, and 21, McGlinch discloses the hub assembly (30) comprising a manifold (32) with a distal portion including the first material where the IFM is disposed about the distal portion of the manifold. A strain relief member (34) is integrally formed with the manifold (col. 3, lines 9-13).

Regarding claims 7-11, and 13, 24 and 25, Gadberry discloses the second material being more compressible than and readily deformable compared to the first material (figs. 3 and 6). The second material is considered elastomeric and the IFM is disclosed as an O-ring (col. 4, lines 25-27). The O-ring can be considered a bead adhered to the first material or an elongated elastomeric sleeve.

Regarding claim 26, McGlinch discloses an elongate medical device packaging assembly (fig. 1) comprising: a tubular member (10) having a lumen (14) defined by an inner surface; an elongate shaft (22) having a proximal portion, a hub assembly (30) connected to the proximal portion of the elongate shaft and including a portion manufactured from a first material (col. 3, lines 13-18); and an IFM (40) disposed about a portion of the hub assembly and configured to form an interference fit with the inner surface of the tubular member when the elongate shaft and the IFM are disposed within the lumen of the tubular member (fig. 1). McGlinch does not disclose the IFM including a second material; however, Gadberry discloses a similar elongate medical device packaging assembly (10) having a tubular member (23) with an IFM (65) including a second material (figs. 3 and 6, the IFM is readily deformable compared to the tubular member). It would have been obvious to one having ordinary skill in the art at the time of the invention to have substituted the IFM (65) including a second material of Gadberry for the IFM (40) of McGlinch in order to create an air tight seal when enclosing the elongate medical device as taught by Gadberry (col. 5, lines 33-36).

5. Claim 12 is finally rejected under 35 U.S.C. 103(a) as being unpatentable over McGlinch and Gadberry as applied to claims 1 and 11 above, and further in view of Roll.

Regarding claim 12, McGlinch and Gadberry do not disclose the O-ring (65) comprising silicone; however, Roll discloses a similar elongate medical device (fig. 2) suitable for packaging in a tubular member (106) with an O-ring (105) formed of rubber (abstract, line 19). Silicone is a form of rubber. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used silicone to form

the O-ring used in the elongate medical device of McGlinch and Gadberry as it is well known in the art. It has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Response to Arguments

6. Applicant's arguments, filed October 29, 2008, have been fully considered but they are not persuasive.

Regarding applicant's arguments of the 102(b) rejection by Roll, the examiner respectfully disagrees. As can be seen in fig. 2 Roll, the shaft (113) is directly attached to the hub assembly (104); hence, it can be said that the shaft is a part of the hub assembly. Since the shaft (113) and hub assembly (104) are constructed of the same first material, it can also be said that the IFM (105) including a second material is disposed about at least a part of a portion of the hub assembly. Therefore, Roll anticipates the limitations as written in claims 1, 7-13, and 26.

Regarding applicant's arguments of the 103(a) rejection over McGlinch and Gadberry, the examiner respectfully disagrees. Gadberry teaches providing an IFM (O-ring 65) used to form a seal between two parts of a medical device to protect its contents. Applicant's argument is not on point, because the rejection as described above is simply replacing the IFM of McGlinch (which is in the exact location and accomplishes the identical function as disclosed by applicant) with the IFM which is made of an elastomeric material (which is a material distinctly different from the material comprising the rest of the elongate medical device) of Gadberry; hence, the fact that the

IFM of Gadberry is used between a cap (27) and a housing (25) instead of the catheter itself is irrelevant.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA L. LALLI whose telephone number is (571)270-5056. The examiner can normally be reached on Monday-Friday 7:30 AM-5:00 PM (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on (571) 272-4562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa L Lalli/
Examiner, Art Unit 3728

/Mickey Yu/
Supervisory Patent Examiner, Art Unit 3728

MLL